



Rulemaking for Methylene Chloride and n-Methylpyrrolidone (NMP) under the Toxic Substances Control Act (TSCA)

**Pre-Panel Outreach
March 17, 2016**



Today's Discussion

- Background:
 - Consultation with Small Entity Representatives
 - TSCA Work Plan for Chemical Assessments
- Methylene Chloride and n-Methylpyrrolidone (NMP)
- Toxic Substances Control Act (TSCA) Section 6(a)
 - Background
 - Developing the Regulations
- Affected entities and potential compliance costs
- Contact information
- Your feedback
- Appendix: Regulatory History and International Action



Background: Consultation with Small Entity Representatives

- EPA is interested in not only information, but also advice and recommendations from the small entity representatives (SERs)
- EPA will use this information to develop a regulatory flexibility analysis, which becomes part of the record for the proposed regulation
- Key elements in this analysis:
 - Number of small entities to which the proposed rule would apply
 - Projected compliance requirements of the proposed rule
 - Identification of all relevant Federal rules which may duplicate, overlap or conflict with the proposed rule
 - Any significant alternatives to the proposed rule which accomplish the stated objectives and which minimize significant economic impact of the proposed rule on small entities



SERs and the Regulatory Process

- We are seeking information on how the options presented might impact your business or organization
 - Provide specific examples of impacts
 - Provide cost data, if available
- We are also seeking alternative methods of regulating these risks
 - Suggest other relevant options, including data on their costs and information on how to ensure compliance
 - Suggest ways that small businesses could benefit from flexibilities, such as different compliance timetables, simplified reporting requirements, and exemptions
- We would like to minimize duplication
 - Provide information on any duplicative or contradictory Federal regulations you are aware of



Background: TSCA Work Plan for Chemical Assessments

- EPA has identified a subset of existing chemicals as a high priority for risk assessment
- 2012-2013:
 - With input from stakeholders, EPA identified a subset of chemicals for assessment, known as the TSCA Work Plan, and described the methodology for how they were prioritized
 - Performed problem formulation for five Work Plan chemicals, developed draft risk assessments for peer review, and released them for public comment.



Background: TSCA Work Plan for Chemical Assessments

- 2014-2015:
 - Released first final risk assessments (TCE, methylene chloride, NMP, antimony trioxide, HHCB)
 - No risks found for uses assessed for antimony trioxide and HHCB.
 - Risks found for uses assessed for TCE, methylene chloride, and NMP. Risk management process began.
 - Refreshed Work Plan with updated exposure information; currently contains 90 chemicals
- 2015-2016:
 - Problem formulation and data needs assessment issued for several flame retardant clusters
 - Problem formulation issued for 1,4-Dioxane
 - Draft risk assessment for 1-bromopropane (planned release) for public comment



Overview: Methylene Chloride and NMP

- EPA assessed Methylene Chloride and NMP paint removal uses as part of the TSCA Work Plan for Chemical Assessments.
- Methylene Chloride
 - Volatile, colorless liquid, non-flammable, non-explosive, non-corrosive, inexpensive.
 - Used frequently as a solvent; also in adhesives, metal cleaning, chemical processing, pharmaceuticals.
 - 25% of methylene chloride in the US used in paint removers (66.3 million lbs annually), down from 50% in 1980s.
- NMP
 - Mildly volatile, colorless liquid, low flammability, non-explosive.
 - Used frequently as a solvent; also in adhesives, leather and brush cleaners, manufacturing of circuit boards, pesticides, petrochemical processing.
 - 9% of NMP in the US used in paint removers (16.6 million lbs annually).
 - Frequently an alternative to methylene chloride paint removers.



	Methylene Chloride Key Information	NMP Key Information
Notes on Use	Used for decades; nonflammable; works quickly Cause of death for ~1 worker/year during bathtub refinishing + suspected additional deaths during other paint removal jobs Inhalation exposure; extremely volatile	Marketed as safer & greener than methylene chloride Works more slowly Exposure is primarily dermal, but also via inhalation
Manufacturers & Users	2 manufacturers, 7 product formulators 5,000 workers in graffiti removal & other outdoor uses 8,000 workers as home contractors (including 1,300 bathtub refinishers) 32,000 workers in commercial/industrial facilities 2.4 million consumer users	6 manufacturers, 14 product formulators 46,000 workers in graffiti removal & other outdoor uses 7,000 workers as home contractors 1,400 workers in commercial/industrial facilities 1.4 million consumer users
Health Effects and Risks of Concern	Acute effects: Neurotoxicity - confusion, incapacitation, and death Chronic effects: Cancer and liver toxicity Inhalation exposures are 2-3 orders of magnitude from target benchmarks Risks for bystanders due to inhalation exposures	Concern is for women of child-bearing age High dose acute effects: Fetal death Lower dose chronic effects (developing fetus): Low birthweight, delayed ossification, growth retardation.
Substitutes	Alternative processes (Heat guns, mechanical sanding, hydroblasting, media blasting (starch, soda, etc)) Chemical substitutes (Benzyl alcohol, dibasic esters, acetone-toluene-methanol formulations, caustics) Generally, hazards of substitutes are of less concern	
Notable Regulations	OSHA PEL 25 ppm Banned for graffiti use in 12 states Listed under California Safer Consumer Products regulation Prohibited for residential & consumer use in the EU	No OSHA PEL California PEL 1 ppm + gloves On the EU candidate list of substances of very high concern



Risk Assessment: Methylene Chloride

- Final TSCA Work Plan Chemical Risk Assessment: August 2014
 - Followed Agency peer review process of publishing a public draft, peer review, and response to peer review and public comment
- Risk assessment identified inhalation risks from paint removers containing methylene chloride:
 - Chronic exposure effects: cancer and liver toxicity
 - Acute exposure effects: Neurotoxicity - confusion, incapacitation, and death
 - Risks from chronic (lifetime) exposure in majority of scenarios except when personal protective equipment (respirator) is worn in low exposure scenarios.
 - Risks from acute high-end exposure (small, enclosed room with poor ventilation, such as a bathroom).
 - Risks to non-users (bystanders and adjacent workers) except in lowest exposure scenarios.
- See: <http://www.epa.gov/assessing-and-managing-chemicals-under-tsca/assessments-tsca-work-plan-chemicals#dcm>



Risk Assessment: Methylene Chloride

- Risks were identified for most worker and consumer exposure scenarios.
- For **non-cancer risks** a **margin of exposure (MOE)** method was used to determine the presence or absence of risk for both acute and chronic exposure scenarios.
 - The benchmark MOE used in the methylene chloride risk assessment is 10.
 - This benchmark constitutes 3x residual uncertainty in extrapolating from animals and 3X residual uncertainty for variability in humans
 - People exposed are considered to be at risk when MOEs are below the benchmark MOE of 10.
 - MOEs and risks calculations for non-cancer effects are explained on the next slide
- For **cancer risks**, the inhalation unit risk (IUR) was used to estimate excess cancer risks for inhalation occupational exposure scenarios.
 - The excess cancer risk is the product of the exposure concentration and the IUR
 - Protecting against non-cancer risks protects against these cancer risks
 - Risk calculations for cancer are explained on the next slide



Risk Calculation (Non-Cancer)

Non-Cancer MOE compared to benchmark MOE (uncertainty factors, or UFs)

MOE (acute or chronic) = $\frac{\text{Non-Cancer Hazard Value (Point of Departure)}}{\text{Human Exposure (ppm)}}$

Where: Hazard Value

POD = Human equivalent dose (ppm)

MOE = Margin of exposure (unitless)

- The lower the exposure the higher the MOE.
- The *lower* the calculated MOE value, the higher the risk
- Cause for concern increases the lower the scenario's risk value (MOE) is below the benchmark MOE



Risk Calculation (Cancer)

Cancer

$$\text{Risk} = \text{Human Exposure} \times \text{IUR}$$

Where:

- Risk = Cancer risk (unitless)
- Human exposure = Exposure estimate (LADC in ppm) from occupational exposure assessment
- IUR = inhalation unit risk ($a \times 10^*$ ppm)

* The *higher* the calculated risk value, the higher the risk

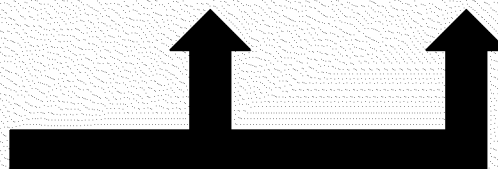
* Cause for concern increases the more the scenario's cancer risk value is above the cancer benchmark



Risk Estimates: Methylene Chloride

Industry	Benchmark MOE (acute & chronic)	MOE acute exposure	MOE chronic exposure, non- cancer	Cancer estimate
Professional Contractors	10	0.015	0.050	1.9 in 1,000
Automotive Refinishing	10	0.11	0.34	2.9 in 10,000
Furniture Refinishing	10	0.035	0.13	7.7 in 10,000
Aircraft Paint Stripping	10	0.012	0.039	2.5 in 1,000
Graffiti Removal	10	0.037	0.16	6.3 in 10,000
Other workplace settings (immersion stripping)	10	0.0063	0.021	4.6 in 1,000

*The lower this number is below 10,
the greater the risk (numbers
above 10 indicate no non-cancer
risks of concern)*



*The larger this number is,
the greater the risk*



Acceptable Exposure Limit (AEL): Methylene chloride



Exposure Estimates: Methylene Chloride

Industry	Acceptable exposure limit (8 hr TWA, ppm)	Acute high-end estimated exposure (8 hr TWA, ppm)	Chronic high-end estimated exposure (8 hr TWA ppm)
Professional Contractors	0.2	858	431
Automotive Refinishing	0.2	120	64
Furniture Refinishing	0.2	364	169
Aircraft Paint Stripping	0.2	1,095	551
Graffiti Removal	0.2	342	139
Other workplace settings (immersion stripping)	0.2	2,015	1009



Risk Assessment: NMP

- NMP is often marketed as a “safer” alternative to Methylene Chloride
- Final TSCA Work Plan Chemical Risk Assessment: March 2015
 - Followed Agency peer review process of publishing a public draft, peer review, and response to peer review and public comment
- Risk assessment identified dermal (liquid or vapor through skin) and inhalation exposure risks from the use of paint removers containing NMP:
 - Developmental effects (acute: fetal mortality; chronic: reduced fetal body weight). Concern is for women of child-bearing age.
 - Chronic exposure risks if used:
 - More than 8 hours per day for more than 5 consecutive days, even if specialized protective gloves are worn
 - More than 4 hours per day, for more than 5 consecutive days, if specialized protective gloves are not worn
 - Acute exposure risks if used:
 - More than 8 hours on a single day, even if specialized protective gloves are worn
 - More than 4 hours on a single day, if specialized protective gloves are not worn
 - No risks to bystanders
- See <http://www.epa.gov/assessing-and-managing-chemicals-under-tsca/assessments-tsca-work-plan-chemicals#completed>



Risk Assessment: NMP

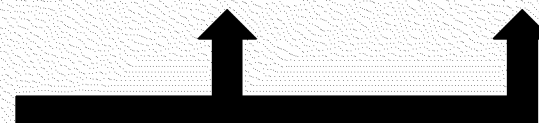
- Risks were identified for a number of worker and consumer exposure scenarios.
 - No risks identified for workers or residents who may be located nearby those that are working with NMP-based paint removers.
- To determine the presence or absence of non-cancer risks for both **acute and chronic exposures**, the **margin of exposure (MOE)** method was used to evaluate the risk
 - The benchmark MOE used for the NMP risk assessment is 30.
 - This benchmark constitutes 3x residual uncertainty in extrapolating from animals and 10X residual uncertainty for variability in humans
 - People exposed are considered to be at risk when MOEs are below the benchmark MOE of 30.
 - See earlier slide for an explanation of MOEs and risks calculations for non-cancer effects



Risk Estimates: NMP

Scenario (covers several industries, assumes no gloves used)	Benchmark MOE (acute & chronic exposure)	MOE– acute exposure	MOE chronic exposure, non-cancer effects
Miscellaneous stripping Assumed mostly indoor, high end of range 1.0 weight fraction 890 cm ² skin surface area, 8 hours	30	0.7	0.1
Graffiti removal Assumed mostly outdoor but may include semi-confined spaces, high end of range 1.0 Weight fraction 890 cm ² Skin surface area, 8 hours	30	0.7	0.1
Miscellaneous stripping Assumed mostly indoor, mid end of range 0.625 weight fraction, 668 cm ² skin surface area, 4 hours	30	13.7	5.4
Graffiti removal Assumed mostly outdoor but may include semi-confined spaces, mid end of range 0.625 weight fraction, 668 cm ² skin surface area, 4 hours	30	14.1	6.1

The lower these numbers are from 30, the greater the risk (numbers above 30 indicate no risks of concern)





Acceptable Exposure Limit (AEL): NMP



From Risk Assessment to Risk Reduction

Risks identified
Methylene chloride and NMP
found to pose risks when used
in typical commercial and
consumer scenarios

Risk reduction needed
Methylene chloride: Exposures
are 100 to 1,000 times greater
than acceptable exposure levels
NMP: Exposures are 5 – 10
times greater acceptable
exposure levels

Approach chosen
Regulation under TSCA
Section 6(a) is the approach
most likely to reduce risks to
workers and consumers



Background: TSCA Section 6(a)

- Provides EPA with the authority to prohibit or limit the manufacture, processing, distribution in commerce, use or disposal of a chemical or mixture.
- EPA must make certain findings before a section 6(a) rule may be finalized:
 - There is a reasonable basis to conclude that a chemical substance or mixture “presents or will present an unreasonable risk of injury to health or the environment.”
 - The regulatory option chosen is the least burdensome option that adequately protects against such risk.



Options Under TSCA Section 6(a)

- Prohibit or limit manufacture, processing or distribution in commerce.
- Prohibit or limit for particular use or above a set concentration.
- Require warnings and instructions.
- Require recordkeeping and testing.
- Prohibit or regulate manner or method of commercial use.
- Prohibit or regulate manner or method of disposal.
- Direct manufacturers/processors to give notice of risk to distributors and users and replace or repurchase.



Uses Under Consideration

- Uses considered for regulation under TSCA Section 6(a) are commercial and consumer paint removers containing methylene chloride or NMP.
- Examples of small business uses:
 - Automotive, aircraft, and marinecraft body paint, and interior repair and maintenance
 - Flooring contractors
 - Furniture repair and refinishing
 - Painting and wall covering contractors
 - Bathtub refinishing



Potentially Impacted Sectors

- Ship building and repairing
- Aircraft manufacturing and repairing
- Museums
- Independent artists, writers, and performers
- Automotive body, paint, and interior repair and maintenance
- Flooring contractors
- Reupholster and furniture repair
- Painting and wall covering contractors
- Paint remover processors or formulators



Developing Potential Regulatory Options

- Over the past year, EPA has identified regulatory options under Section 6(a) of TSCA that would provide adequate protection from the risks identified
- Stakeholders we've been working with:
 - Affected States and Tribes
 - Chemical manufacturers, product formulators, and their trade associations
 - Commercial paint remover users in various sectors
- Generally, alternatives are available and being used successfully throughout several industries
- What we've heard, from stakeholders and from industry research:
 - Marinecraft:
 - Paint is generally not removed to the substrate; when needed, sand or soda blasting are used.
 - Chemical stripping requires consideration of disposal (heavily regulated near water).
 - Aircraft:
 - Use of methylene chloride is declining, particularly among large scale users, due to air regulations and other considerations.
 - Refinishing of small aircraft still use methylene chloride, though many now use benzyl alcohol formulations.
 - Renovations and contractors:
 - Many firms have stopped using methylene chloride due to worker safety concerns, potential for fatal accidents, odor (employee and client complaints), and specialized PPE, training, and waste disposal needed.
 - Some firms use MC only outdoors or with fans for ventilation
 - Alternatives identified tend to be mechanical methods or benzyl alcohol.
 - Automotive (collision repair and autobody):
 - Chemical removers do not appear to be critical for this sector as industry reps reported large use of abrasives for paint removal
 - Furniture refinishing:
 - Seem to exclusively use methylene chloride, with some attempts at alternatives containing acetone.
 - There are flammability concerns with substitutes given the prevalence of wood substrates



Developing Potential Regulatory Options

- From over 50 options analyzed, the two options presented today would provide risk reduction to target benchmarks
- Other options considered **do not** reduce exposure to benchmark risk levels

Option	Why it does not provide sufficient risk reduction
Limiting concentration of methylene chloride or NMP in a formulation	Even when reduced to 5% concentration, for typical work scenarios (>4 hours), workers would be at acute risk
Prohibiting certain formulations (such as spray) to reduce inhalation exposure (methylene chloride only, since NMP exposures are primarily dermal)	For methylene chloride, most acute and cancer risk would remain.
Requiring local exhaust or other ventilation (without personal protective equipment)	Alone, ventilation does not reduce exposures to benchmark risk levels.
Requiring PPE at APFs lower than 1,000 or 10,000 (methylene chloride only)	1) Only air-supplied respirators can effectively reduce exposures 2) Below APF 1,000, exposures are not reduced to benchmark risk levels.
Requiring record keeping and testing	Alone, this does not provide protection from risks
Requiring labeling of products	The particular actions the label would need to require are not likely to be followed properly. Exposures would not be reduced to benchmark risk levels.



Potential Regulatory Options

1. Prohibit manufacturing, distribution, and use of methylene chloride or NMP as a paint remover
2. Allow commercial use with PPE and other restrictions
 - Methylene chloride:
 - Supplied air respirator (APF 1,000 in most situations, APF 10,000 for immersion stripping).
 - Some uses would also require engineering controls
 - All workers at risk of exposure would need to wear respirators. Exposure would be determined by monitoring.
 - APF is the workplace level of respiratory protection that a respirator or class of respirators is expected to provide to employees. For example, APF 1,000 reduces the exposure concentration by 1,000 times.
 - Bystanders (such as residents of homes) must stay out for up to 24 hours
 - Workplaces would have the option of meeting an exposure limit (potentially could use engineering controls to reduce the respirator APF needed)
 - NMP:
 - Require concentration limits on NMP in paint removers (25%), formulator testing to identify protective gloves for their products, and PPE requirements
 - PPE: Workers wear specialized gloves and, indoors, a respirator of APF 10.
 - All workers at risk of exposure would need to wear respirators. Exposure would be determined by monitoring.
 - Workplaces have the option of meeting an exposure limit of 1 ppm + specialized gloves, instead of the respirator with APF 10



Risk Reduction of Regulatory Options

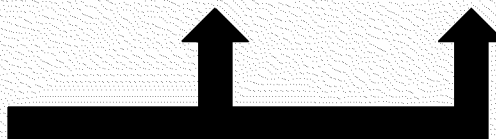
1. Prohibit manufacturing, distribution, and use of methylene chloride or NMP as a paint remover
 - Risks eliminated; complete risk reduction
2. Allow use with PPE and other restrictions
 - Methylene chloride:
 - Eliminates risks for bystanders (residents of homes, for example) because they are excluded from the area
 - Reduces risks to benchmarks for workers
 - NMP:
 - Reduces risks to benchmarks for workers



Risk Reductions: Methylene Chloride PPE option

Industry	Benchmark MOE (acute & chronic exposure)	APF 1,000 Risk estimate – acute	APF 1,000 Risk estimate – chronic non- cancer	APF 1,000 Cancer estimate
Professional Contractors	10	15	50	1.9 in 1,000,000
Automotive Refinishing	10	110	337	2.9 in 10,000,000
Furniture Refinishing	10	35	128	7.7 in 10,000,000
Aircraft Paint Stripping	10	12	39	2.5 in 1,000,000
Graffiti Removal	10	37	156	6.3 in 10,000,000
Other workplace settings (immersion stripping) (APF 10,000 or 1,000 + ventilation)	10	63 (APF 10,000)	215 (APF 10,000)	4.6 in 10,000,000 (APF 10,000)

*All these numbers are now above 10,
indicating no non-cancer risks of concern*



*All these numbers now indicate no
cancer risks of concern*





Risk Reductions: NMP PPE Option

Scenario	Industry/ Activity	Exposure	PPE required to achieve MOE Greater Than the Benchmark MOE
Baseline (high end of current exposures)	Miscellaneous stripping	Acute	Not achievable
		Chronic	Not achievable
	Graffiti removal	Acute	Not achievable
		Chronic	Not achievable
With Maximum 25% NMP in products and no ventilation indoors	Miscellaneous stripping	Acute	Gloves
		Chronic	Gloves + APF 10
	Graffiti removal	Acute	Gloves
		Chronic	Gloves

- In all scenarios evaluated, without gloves and without a respirator or ventilation there are risks of concern.
 - In some scenarios (indoors) the MOE with gloves and APF 10 is greater than the benchmark MOE and “gloves + APF 10” is shown in the table signifying no significant risks when wearing gloves.
 - In some scenarios (outdoors) the MOE with gloves is greater than the benchmark MOE and “gloves” is shown in the table signifying no significant risks when wearing gloves.
 - Based on modeling and underlying assumptions, in some scenarios the exposure reduction of gloves combined with the most protective respirator (APF 10,000) would not reduce exposure sufficiently to achieve an MOE above the MOE baseline. In those cases “not achievable” is shown.
- Refer to Table 2-3 in the Final Risk Assessment for exposure durations and air concentrations used to assess risks.



Costs: Methylene Chloride Prohibition

- Costs include costs to manufacturers, processors and to commercial users
- Changing products to remove methylene chloride (chemical substitution in formulation, relabeling, and other changes) (*applies to manufacturers, processors*) + downstream notification about prohibited uses (*applies to manufacturers, processors, distributors*)
 - 2 manufacturers, 7 formulators
 - First-year costs: \$181,000, or annualized cost: \$15,000 (over 20 years)
- Costs associated with switching to substitutes (*commercial users*)
 - Process change
 - For some firms this is expected to be minimal if they have experience with using alternative chemicals or paint removal methods.
 - Other firms will likely have a trial and error period until they find an alternative chemical or mechanical means that meets the needs of their work process.
 - Hazards of substitutes
 - Substitutes present some hazards, but generally less than methylene chloride.
 - Job time when using substitutes (*all users*). This is a cost or savings, depending on job specifics
 - Depending on the job, the time needed could increase or decrease. This is based on the type and number of coatings, surface prep, clean-up, dwell time, and other factors.
- **Total cost (for all commercial entities):**
 - **\$15,000 per year** + qualitative inconvenience, hazards of substitutes, and increased time
 - First year monetized costs: \$181,000



Methylene Chloride Prohibition: Changing to Substitute Chemicals

- Currently assuming there is a viable chemical alternative for all industry sectors
 - We are seeking information to confirm or change these assumptions
- Current cost estimates show a cost **savings** per firm when switching from methylene chloride to an alternative chemical paint remover in all industry sectors
 - On a per ounce basis, some chemical alternatives are less expensive than methylene chloride
 - In some situations, less of the alternative product is needed (compared with methylene chloride) for the same job (example: benzyl alcohol products)



Costs: Methylene Chloride PPE

- Costs include costs to manufacturers, processors and to users
- Downstream notification about prohibited uses (*manufacturers, processors, distributors*)
 - 2 manufacturers, 7 formulators
 - First-year costs: \$2,000, or annualized cost: \$60 (over 20 years)
- Commercial users (total costs and for small businesses)
 - Total Annualized Cost: \$33.6 million
 - Cost per employee of worker PPE of air supplied respirator (includes device, fitting, training, medical monitoring, etc).
 - For most industries, this would be APF 1,000
 - For immersion stripping, this would be APF 10,000
 - If work is performed in a residence, homeowners are not permitted in the home while work is performed and for a period of at least 24 hours after work is completed
 - PPE Cost estimates:
 - Art Restoration & Conservation: \$94,000 (\$56,000 total first year costs) (\$1,026 per small firm)
 - Automotive: \$366,000 (\$220,000 total first year cost) (\$1,020 per small firm)
 - Furniture Refinishing: \$11,930,000 (\$7,200,000 total first year cost) (\$1,005 per small firm)
 - Bathtub Refinishing: \$1,591,000 (\$950,000 total first year cost) (\$1,056 per small firm)
 - Professional Contractors: \$19,491,000 (\$18,000,000 total first year cost) (\$1,013 per small firm)
 - Aircraft Repainting: \$289,000 (\$167,000 total first year cost) (\$1,095 per small firm)
 - Ship Repainting: \$60,000 (\$35,000 total first year cost) (\$1,091 per small firm)
 - Graffiti Removal: \$237,000 (\$136,000 total first year cost) (\$1,000 per small firm)



Costs: NMP Prohibition

- Costs include costs to manufacturers, processors and to users
- Changing products to remove NMP (chemical substitution in formulation, relabeling, and other changes) (*applies to manufacturers, processors*) + downstream notification about prohibited uses (*applies to manufacturers, processors, distributors*)
 - 6 manufacturers, 14 formulators
 - First-year costs: \$316,000, or annualized cost: \$20,000 (over 20 years)
- Costs associated with switching to substitutes (*commercial users*)
 - Materials replacement (*commercial users*)
 - Commercial costs: \$728,000 annually (Cost of switching to an alternative chemical paint remover)
 - Depending on the job, the time needed could increase or decrease. This is based on the type and number of coatings, surface prep, clean-up, dwell time, and other factors
 - Process change for substitutes (*commercial users*)
 - For some firms this is expected to be minimal if they have experience with using alternative chemicals or paint removal methods.
 - Other firms will likely have a trial and error period until they find an alternative chemical or mechanical means that meets the needs of their work process.
 - Hazards of substitutes
 - Substitutes present some hazards, but generally less than NMP
- **Total cost (for all commercial users):**
 - **\$728,000** + inconvenience and hazards of substitutes
 - First year monetized costs: \$316,000



Costs: NMP reformulations & PPE

- Costs include costs to manufacturers, processors and to users
- Changes to product formulation, relabeling, and other changes (*manufacturers, processors*) + downstream notification (*manufacturers, processors, distributors*)
 - 6 manufacturers, 14 formulators
 - First-year costs: \$316,000, or annualized cost: \$20,000 (over 20 years)
- Commercial users (total costs and for small businesses)
 - Total Annualized Cost: \$4.7 million
 - Cost per employee of worker PPE (specialized gloves and respirator with APF 10 (includes device, fitting, training, etc))
 - Cost estimates:
 - Art Restoration & Conservation: \$83,000 (\$64,000 total first year cost) (\$275 per small firm)
 - Automotive: \$2,000 (\$1,000 total first year cost) (\$186 per small firm)
 - Furniture Refinishing: \$840,000 (\$720,000 total first year cost) (\$543 per small firm)
 - Bathtub Refinishing: \$0 (NMP is not used on bathtubs)
 - Professional Contractors: \$2,437,000 (\$1,900,000 total first year cost) (\$913 per small firm)
 - Aircraft Repainting: \$0 (NMP is not used on aircraft)
 - Ship Repainting: \$0 (NMP is not used on marine craft)
 - Graffiti Removal: \$1,306,000 (\$867,000 total first year cost) (\$608 per small firm)



Contact Information

- For paint removers rulemaking:
 - Niva Kramek, 202-564-2897, kramek.niva@epa.gov
 - Joel Wolf, 202-564-0432, wolf.joel@epa.gov
- For SBAR:
 - Nathaniel Jutras, RFA/SBREFEA staff contact
EPA Office of Policy
202-564-0301
Jutras.Nathaniel@epa.gov
- All Work Plan Chemical risk assessments:
<http://www.epa.gov/assessing-and-managing-chemicals-under-tsca/assessments-tsca-work-plan-chemicals>



Regulatory History and International Action

APPENDIX



Regulatory History of Methylene Chloride at EPA

- **Waste:**
 - Listed as toxic (non-acute) hazardous waste under the Resource Conservation and Recovery Act.
 - Listed on the Toxics Release Inventory.
- **Air:**
 - Listed as a hazardous air pollutant (HAP) from several different emission sources.
 - 2008: Source rule for paint stripping & misc. surface coating operation established standards for using methylene chloride to remove dried paint; implemented management practices to minimize emissions.
 - 1995: NESHAP for large aerospace paint removal operations; updated 2015.
- **Water:**
 - 2010: Maximum Contaminant Level set under the Safe Drinking Water Act at 5 ppb.



Regulatory History of NMP at EPA

- Listed on the Toxics Release Inventory.
- Listed under Clean Air Act Section 111: Standards of Performance for New Stationary Sources of Air Pollutants – Equipment Leaks Chemical List.
- Approved for use as a pesticide inert ingredient (food & nonfood uses).



Methylene Chloride: Other Agencies

- **Occupational Safety and Health Administration (OSHA)**
 - 2000: Facilities using methylene chloride must use vapor control equipment. When using methylene chloride off-site (e.g. home renovations), air tests, improved ventilation engineered controls, and personal protective equipment (including full-face atmosphere-supplying respirators) must be used.
 - 1997: A lower Permissible Exposure Limit (PEL) was set in 1997 for paint removal in furniture operations (from 500 ppm to 25 ppm).
- **National Institutes for Occupational Safety and Health (NIOSH)**
 - 2013: Issued a hazard alert for methylene chloride bathtub refinishing use, highlighting the fatalities caused by this specific application.
 - 2000: Listed methylene chloride as a potential carcinogen.
- **Consumer Product Safety Commission (CPSC)**
 - 2013: Public fact sheet on paint strippers highlighting risks of methylene chloride.
 - 1988: Warning labels required on all products containing more than one percent methylene chloride. The cautionary labeling requirements note potential cancer hazard, factors that contribute to risk, and safeguards such as using the product in a well-ventilated area. Personal protective equipment (PPE) information is not listed.
- **Food and Drug Administration (FDA)**
 - 1989: Banned methylene chloride as an ingredient in all cosmetic products; had been used in aerosol cosmetic products such as hairspray.
- **Housing and Urban Development (HUD)**
 - Hazardous chemicals (including methylene chloride) prohibited from use for lead paint removal in enclosed spaces.



NMP: Other Agencies

- OSHA: No PEL established
 - California: State PEL of 1 ppm
- CPSC: Public fact sheet about paint strippers, including hazards of NMP and recommendations for personal protective equipment (created in 2013; updated in 2015)



Sample of State Regulations

State	Methylene Chloride	NMP
Alaska	Listed as a carcinogenic hazardous substance	
California	Listed by Proposition 65; listed as an informational candidate under CA's Safer Consumer Products regulations; designated chemical for biomonitoring.	Listed by Proposition 65; PEL at 1 ppm in an 8-hr TWA; requires employees to wear appropriate gloves; listed as an informational candidate under CA's Safer Consumer Products regulations.
Florida	Listed as a liver carcinogen.	
Indiana, Iowa, South Carolina	Established detection monitoring regulations.	
Minnesota	Chemical of high concern	Chemical of high concern
New Hampshire		Toxic air pollutant
New Jersey		Hazardous substance
Pennsylvania	Listed as 'environmental' and 'special' hazard (for carcinogenicity).	Hazardous substance
Vermont		Air pollutant
Washington	Chemical of high concern under Children's Safe Products Act; regulated to minimize occupational exposure	Chemical of high concern under Children's Safe Products Act



Sample of International Regulations & Classifications

State	Methylene Chloride	NMP
EU	<p>2010: Incorporated restrictions for use in paint strippers. Banned from use in concentrations greater than 0.1% in products for consumers / professionals unless professionals are appropriately licensed and trained.</p> <p>2012: Industrial operations must have appropriate ventilation, evaporation minimization, training, PPE May be some exceptions to these restrictions in certain countries (like UK).</p> <p>Will be considered Carcinogen 2 under REACH</p>	<p>Candidate list of substances of very high concern for authorization in the EU.</p> <p>Proposed for restrictions under REACH on concentrations higher than 0.3%. Ongoing discussions.</p>
Canada	<p>2003: published code of practice to reduce methylene chloride emissions from paint strippers in commercial operations.</p> <p>1999: Required pollution prevention plans for all persons using methylene chloride in several activities (including aircraft paint stripping).</p>	<p>High priority chemical to be addressed under CMP3, post-2016.</p>
Australia		<p>Subject of Tier II health risk assessment; subject to labeling and related requirements.</p>
IARC	<p>Will be considered a probable human carcinogen</p>	